OCT 1 1 2000



# 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K002613

1. **Submitter's Identification:**

Mr. Fangyi Liu
Jiangsu Intco Medical Equipment & Supply Co., Ltd.
No. 1 Suiguan Road
Danyang City, Jiangsu Province 212300
P.R. China

Date Summary Prepared: August 18, 2000

2. **Name of the Device:**

Jiangsu Intco Medical Equipment & Supply Co., Ltd.

**EZ-Comfort™ Transporter 2000 Series**

3. **Predicate Device Information and Substantial Equivalence:**

Jiangsu Intco Medical Equipment & Supply Co. **EZ-Comfort™ Transporter 2000 Series** is substantially equivalent in safety and effectiveness to the Invacare Corporation Tracer series of Manual Wheelchair (K935398).

4. **Intended Use:**

The intended use of Jiangsu Intco Medical Equipment & Supply Co., Ltd. **EZ-Comfort™ Transporter 2000 Series** is to provide mobility to persons limited to a sitting position.

5. **Device Description:**

Classified by FDA's Physical Medicine panel as Class I, 21 CFR 890.3850, Wheelchair (Mechanical), product code is IOR. The Jiangsu Intco Medical Equipment & Supply Co., Ltd. **EZ-Comfort™ Transporter 2000 Series** is wheelchair that provides mobility to persons limited to a sitting position. It consist a rigid, mechanical, Aluminum Alloy frame and canvas upholstery that meets EN1021-1: Assessment of the Ignitability of Upholstered Furniture. It has two 8" rear wheels and two 8" front casters for turning and maneuverability, a fold-down back allows the chair to fit in compact spaces..

K002673

## 6. Technological Characteristics Summary:

The standards used for Jiangsu Intco Medical Equipment and Supply Co., Ltd. Wheelchair production are based on the following standards:

| | |
|---|---|
| ISO 7176-1 | Wheelchair: Determination of static Stability |
| ISO 7176-3 | Wheelchair: Determination of efficiency of brakes |
| ISO 7176-8 | Wheelchair: Requirements and test methods for static, impact and f fatigue strengths. |
| ISO 7176-11 | Wheelchair: Test dummies. |
| ISO 7176-15 | Wheelchair: Requirements for information disclosure, documentation and labeling. |
| ISO 7176-16 | Wheelchair: Resistance of ignition of upholstered parts— Requirements and test methods. |
| EN 1021-1 | Furniture – Assessment of the Ignitability of Upholstered Furniture. |

## 7. Conclusion:

Jiangsu Intco Medical Equipment & Supply Co., Ltd. **EZ-Comfort™ Transporter 2000 Series** conform fully to the standards which be mentioned in Section 6 as well as applicable 21 CFR references, and, meets pinhole FDA requirements, biocompatibility requirements and labeling claims as shown by data in Section 6. There are no safety/efficacy issues or new claims from the "substantial equivalence" products cited.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 11 2000

Mr. James Chu
Official Correspondent for
Jiangsu Intco Medical Equipment & Supply Company, LTD.
c/o Basic Medical Industries, Inc.
12390 East End Avenue
Chino, California 91710

Re: K002673
Trade Name: EZ-Comfort™ Transporter 2000 Series
Regulatory Class: I
Product Code: IOR
Dated: August 18, 2000
Received: August 28, 2000

Dear Mr. Chu:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Neil R. Ogden for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Attachment A**



510(k) NUMBER (IF KNOWN): K002673
DEVICE NAME: Jiangsu Intco Medical Equipment & Supply Co., Ltd.
INDICATIONS FOR USE: EZ-Comfort™ Transporter 2000 Series

The intended use of Jiangsu Intco Medical Equipment & Supply Co., Ltd. EZ-Comfort™ Transporter 2000 Series is to provide mobility to persons limited to a sitting position.

MRO for cmw
(Division Sign-Off)
Division of General Restorative
510(k) Number K002673

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrent of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use X
(Optional Format 1-2-96)